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NEW RESEARCH CONFIRMS ONCE-A-WEEK REGIMEN EFFECTIVELY CURES TUBERCULOSIS IN SELECT PATIENTS

New data released today by the Tuberculosis Trials Consortium (TBTC) confirms that a once-weekly TB regimen, initiated after the first eight weeks of therapy, is a viable option for selected patients being treated for active TB disease. Supported by the Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, TBTC is a network of 23 clinical research facilities in the United States and Canada.

In this TBTC study, published in the August 17th edition of *The Lancet*, investigators evaluated a regimen of once-weekly isoniazid and rifapentine given during the continuation phase of therapy (from the ninth to twenty-fourth week of treatment), as an alternative to the standard twice-weekly regimen of isoniazid and rifampin in a group of HIV-negative TB patients. TBTC researchers found the once-weekly regimen to be safe and effective for HIV-negative patients without signs of advanced tuberculosis (i.e. those with no lung cavities identifiable on chest x-ray).

To identify those patients in whom a weekly therapy would be possible, more than 1,000 HIV-negative patients with active TB disease completed eight weeks of intensive TB therapy with the four frontline TB drugs – isoniazid, rifampin, pyrazinamide and ethambutol – before being randomly assigned to one of two groups during the 16-week continuation phase of TB treatment. One trial group received isoniazid and rifapentine, the first new TB-specific drug approved by the Food and Drug Administration in 30 years, once a week. The other group received the standard therapy of twice-weekly isoniazid and rifampin.

Both groups of patients were then followed for two years. Nine percent (46 patients) of those who took the once-a-week regimen either relapsed or experienced treatment failure. Six percent (28 patients) who took the twice-weekly regimen relapsed or had a treatment failure.

Overall, the relapse rate in the once-weekly arm was slightly higher. However, when researchers reviewed data on those patients without lung cavities, they found that the relapse rates were comparable (about three percent in both treatment arms). Therefore, researchers were able to identify a group of HIV-negative patients in whom the once-a-week therapy would be as successful as other currently approved treatment regimens.

Since the once-weekly isoniazid and rifapentine regimen is administered less frequently than the standard regimen, adherence may be improved, helping to cure more HIV-negative TB patients and prevent further TB transmission. The once-weekly regimen is not recommended for HIV-infected TB patients.

Investigators at multiple sites in the United States and Canada participated in this study. These included the following:

ARKANSAS

Little Rock: Rebecca Edge Martin, M.D., at the John L. McClellan Memorial Veterans Hospital

ARIZONA

Phoenix: Maricela Moffitt, M.D., at the Maricopa Medical Center Research Foundation.

CALIFORNIA

Los Angeles: Matthew Goetz, M.D., at the Veterans Affairs Greater Los Angeles Healthcare System and Brenda Jones, M.D., at the Los Angeles County/University of Southern California Medical Center.

San Diego: Antonino Catanzaro, M.D., at the University of California San Diego Medical Center.

San Franciso: Peter Jensen, M.D., at the San Francisco Veterans Affairs Medical Center

CANADA

Manitoba: Earl Hershfield, M.D., at the University of Manitoba.

COLORADO

Denver: Randall Reves, M.D., and William Burman, M.D., at Denver Public Health.

DISTRICT OF COLUMBIA:

Washington, D.C.: Fred Gordin, M.D., and Debra Benator, M.D., at the Washington, D.C., Veterans Affairs Medical Center.

FLORIDA

Miami: Gordon Dickinson, M.D., at the Miami Veterans Affairs Medical Center.

GEORGIA

Atlanta: C. Robert Horsburgh, M.D., formerly of the Emory University School of Medicine.

ILLINOIS

Chicago: William Paul, M.D., at the Chicago Department of Public Health; Mondira Bhattacharya, M.D., (Lakeside Division), and David Pitrak, M.D., (Westside) at the Veterans Affairs Chicago Health Care System, Lakeside and Westside Divisions.

Hines: Constance Pachuki, M.D., at the Edward Hines Jr. Veterans Affairs Hospital.

MARYLAND

Baltimore: Richard Chaisson, M.D., and Tim Sterling, M.D., at Johns Hopkins University School of Medicine

NEW JERSEY

Newark: Bonita Mangura, M.D., and Lee B. Reichman, M.D., M.P.H, at The New Jersey Medical School National Tuberculosis Center at the University of Medicine and Dentistry of New Jersey

NEW YORK

New York: Wafaa El-Sadr, M.D., at Harlem Hospital Center, Michael Simberkoff, M.D., at the New York Veterans Affairs Medical Center (NYVAMC) and Neil Schluger, M.D., William Rom, M.D., and Rany Condos, M.D., at New York University Schools of Medicine/Bellevue Hospital.

NORTH CAROLINA

Charlotte: James Horton, M.D., at the Carolinas Medical Center

Durham: Carol Dukes Hamilton, M.D., at the Duke University Medical Center and Durham Veterans Affairs Medical Center (DVAMC).

TENNESSEE

Nashville: Douglas Kernodle, M.D., at the Nashville Veterans Affairs Medical Center.

TEXAS

Fort Worth: Stephen Weis, D.O., the University of North Texas Health Science Center.

Houston: Robert Awe, M.D., and Christopher Lahart, M.D., Houston Veterans Affairs Medical Center.

San Antonio: Marc Weiner, M.D., at the Audie L. Murphy Memorial Veterans Hospital.

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Tuberculosis Trials Consortium

The mission of the Tuberculosis Trial Consortium is to conduct research concerning the diagnosis, clinical management, and prevention of latent TB infection and active TB disease. For more information on TBTC, please visit: http://www.cdc.gov/nchstp/tb/tbtc/default.htm